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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,543	08/04/2002	Lin Cai	2577-138	5048

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 05/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/089,543

Applicant(s)

CAI ET AL.

Examiner

Gerald G. Leffers Jr., PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 April 2002 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/12/2003.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 1-3 are pending in the instant application and are under consideration.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Each of the claims is directed to a promoter that is cotton fiber-specific, comprising the entire promoter for the cotton B-tubulin gene CFTUB2, or a fragment thereof. There is no indication in any of the rejected claims of the "hand of man". Thus, the rejected claims read on products of nature, which is improper. It would be remedial to amend the claim language to include the term "isolated" prior to the word promoter (e.g. "An isolated promoter....").

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 is directed to “the” promoter of the cotton B-tubulin gene CFTUB2. The instant specification teaches the isolation of a 1.433 kb fragment of the CFTUB2 gene that comprises promoter activity (i.e. SEQ ID NO: 2). An ~985 bp fragment of this sequence is also shown to have promoter activity. The instant specification does not clearly define what is “the” CFTUB2 promoter. No further deletion analysis is provided, making it unclear what might be considered as “the” CFTUB2 promoter (i.e. the minimal sequence within SEQ ID NO: 2 that comprises cotton fiber-specific promoter activity). Therefore, the metes and bounds of what constitutes “the” CFTUB2 promoter are unclear.

Claims 1-3 are vague and indefinite in that the metes and bounds of the term “cotton fiber-specific” are unclear. The term is not explicitly defined in the specification as to how much CFTUB2 promoter activity is permitted in non-fiber tissues of cotton is permitted for the claimed promoter to remain “cotton fiber-specific”. Therefore, there is no basis for the skilled artisan to determine whether, for example, a particular fragment of SEQ ID NO: 2 is necessarily cotton fiber-specific.

Claim 2 is vague and indefinite in that the metes and bounds of the phrase “comprising a 1433 kb fragment of the promoter of the cotton B-tubulin gene CFTUB2 having the sequence of SEQ ID NO: 2” are unclear. First, the specification appears to indicate that the characterized fragment of the CFTUB2 promoter is 1,433 *base pairs* (bp) in length (i.e. SEQ ID NO: 2), not 1,433 *kb* in length, as is currently claimed (i.e. not 1,433,000 base pairs in length). Second, it is unclear as the claim is currently written whether the cited phrase specifies that the 1,433 bp fragment is the same as the sequence of SEQ ID NO: 2, or whether it is a different 1,433 bp

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fragment of the CFTUB2 promoter (i.e. “a fragment of the CFTUB2 promoter that comprises the sequence of SEQ ID NO: 2”).

Claim 3 is vague and indefinite in that the metes and bounds of the phrase “comprising a 984 kb fragment of the promoter of the cotton B-tubulin gene CFTUB2 having the sequence of nucleotides 449-1433 of SEQ ID NO: 2” are unclear. First, the specification appears to indicate that the characterized fragment of the CFTUB2 promoter is ~984 *base pairs* (bp) in length (i.e. SEQ ID NO: 2), not 984 *kb* in length, as is currently claimed (i.e. not 984,000 base pairs). Second, it is unclear as the claim is currently written whether the cited phrase specifies that the 984 bp fragment is the same as nucleotides 449-1433 of SEQ ID NO: 2, or whether it is a different 984 bp fragment of the CFTUB2 promoter (i.e. “a fragment of the CFTUB2 promoter that comprises nucleotides 449-1433 of SEQ ID NO: 2”). Finally, isn’t the length of a DNA fragment described by nucleotides 449-1433 of SEQ ID NO: 2 actually 985 bp rather than 984 bp (i.e. the fragment beginning with, and including, nucleotide 449 up to nucleotide 1433)?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Claim 1 is directed to “the” promoter of the cotton B-tubulin gene CFTUB2. The instant specification teaches the isolation of a 1.433 kb fragment of the CFTUB2 gene that comprises promoter activity (i.e. SEQ ID NO: 2). An ~985 bp fragment of this sequence is also shown to have promoter activity. The instant specification does not clearly define what is “the” CFTUB2 promoter. No further deletion analysis is provided, making it unclear what might be considered as “the” CFTUB2 promoter (i.e. the minimal sequence within SEQ ID NO: 2 that comprises cotton fiber-specific promoter activity). Further, since the recited promoter is only referred to by name (i.e. “the CFTUB2 promoter”), the rejected claim can be interpreted as encompassing allelic variants or derivatives of the promoter sequence described by SEQ ID NO: 2. Because the instant specification provides no significant information regarding what minimal sequences or nucleotides are required for the recited promoter to retain promoter activity, much less what nucleotides are required in order to retain “cotton fiber-specific” activity, there is no basis for the skilled artisan to envision variants or derivatives of the CFTUB2 promoter that necessarily retain the recited functional activity.

As indicated above, claims 2-3 can be interpreted as encompassing any 1,433 or 985 nucleotide sequence obtained from a CFTUB2 gene so long as it is derived from a promoter that comprises at least nucleotides 449-1433 of SEQ ID NO: 2. Thus, claims 2-3 encompass any promoter that comprises a fragment of the promoter described by SEQ ID NO: 2 and which has cotton fiber-specific promoter activity (e.g. a promoter that comprises only a portion of nucleotides 449-1433 of SEQ ID NO: 2 and additional 5' or 3' sequences). Such additional 5' or 3' regulatory sequences for the CFTUB2 gene described by SEQ ID NO: 2 have not been described in the instant specification or prior art.

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SEQ ID NO: 2 appears to be novel in the art. Given this novelty, the prior art does not offset the deficiencies of the instant specification with regard to what are the minimal elements within the CFTUB2 promoter described by SEQ ID NO: 2 that are required for promoter activity. Thus, there is no basis in the prior art or instant specification to envision (i) what is the minimal sequence within SEQ ID NO: 2 that comprises promoter activity, much less cotton fiber-specific promoter activity, and (ii) what changes can be made to the promoter described by SEQ ID NO: 2 that would necessarily be expected to retain the recited promoter activity. Therefore, the skilled artisan would reasonably have concluded that applicants were not in possession of the broadly recited genus of CFTUB2 promoters.

### *Conclusion*

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G. Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD  
Primary Examiner  
Art Unit 1636

ggl

  
GERRY LEFFERS  
PRIMARY EXAMINER